4164-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2017-D-1956]

Identifying Trading Partners Under the Drug Supply Chain Security Act; Revised Draft Guidance for Industry; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of availability.

SUMMARY: The Food and Drug Administration (FDA or Agency) is announcing the availability of a revised draft guidance for industry entitled "Identifying Trading Partners Under the Drug Supply Chain Security Act." FDA is issuing this guidance to assist industry and State and local governments in understanding how to categorize the entities in the drug supply chain in accordance with the Drug Supply Chain Security Act (DSCSA). The revised draft guidance explains how to determine when certain statutory requirements will apply to entities that are considered trading partners in the drug supply chain. It also discusses the activities of private-label distributors, salvagers, and returns processors and reverse logistics providers. Additionally, the revised draft guidance discusses the distribution of drugs for emergency medical reasons, office use, non-human research purposes, and research purposes in humans under an investigational new drug application. This guidance revises the August 2017 draft guidance entitled "Identifying Trading Partners Under the Drug Supply Chain Security Act."

DATES: Submit either electronic or written comments on the draft guidance by [INSERT DATE 60 DAYS AFTER DATE OF PUBLICATION IN THE *FEDERAL REGISTER*] to ensure that the Agency considers your comment on this draft guidance before it begins work on the final version of the guidance.

ADDRESSES: You may submit comments on any guidance at any time as follows:

Electronic Submissions

Submit electronic comments in the following way:

- Federal eRulemaking Portal: https://www.regulations.gov. Follow the instructions for submitting comments. Comments submitted electronically, including attachments, to https://www.regulations.gov will be posted to the docket unchanged. Because your comment will be made public, you are solely responsible for ensuring that your comment does not include any confidential information that you or a third party may not wish to be posted, such as medical information, your or anyone else's Social Security number, or confidential business information, such as a manufacturing process. Please note that if you include your name, contact information, or other information that identifies you in the body of your comments, that information will be posted on https://www.regulations.gov.
- If you want to submit a comment with confidential information that you do not wish to be made available to the public, submit the comment as a written/paper submission and in the manner detailed (see "Written/Paper Submissions" and "Instructions").

Written/Paper Submissions

Submit written/paper submissions as follows:

- Mail/Hand delivery/Courier (for written/paper submissions): Dockets Management Staff (HFA-305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.
- For written/paper comments submitted to the Dockets Management Staff, FDA will post your comment, as well as any attachments, except for information submitted, marked, and identified, as confidential, if submitted as detailed in "Instructions."

Instructions: All submissions received must include the Docket No. FDA-2017-D-1956 for "Identifying Trading Partners Under the Drug Supply Chain Security Act." Received comments will be placed in the docket and, except for those submitted as "Confidential

Submissions," publicly viewable at https://www.regulations.gov or at the Dockets Management Staff between 9 a.m. and 4 p.m., Monday through Friday, 240-402-7500.

- Confidential Submissions--To submit a comment with confidential information that you do not wish to be made publicly available, submit your comments only as a written/paper submission. You should submit two copies total. One copy will include the information you claim to be confidential with a heading or cover note that states "THIS DOCUMENT CONTAINS CONFIDENTIAL INFORMATION." The Agency will review this copy, including the claimed confidential information, in its consideration of comments. The second copy, which will have the claimed confidential information redacted/blacked out, will be available for public viewing and posted on https://www.regulations.gov. Submit both copies to the Dockets Management Staff. If you do not wish your name and contact information to be made publicly available, you can provide this information on the cover sheet and not in the body of your comments and you must identify this information as "confidential." Any information marked as "confidential" will not be disclosed except in accordance with 21 CFR 10.20 and other applicable disclosure law. For more information about FDA's posting of comments to public dockets, see 80 FR 56469, September 18, 2015, or access the information at: https://www.govinfo.gov/content/pkg/FR-2015-09-18/pdf/2015-23389.pdf.

Docket: For access to the docket to read background documents or the electronic and written/paper comments received, go to https://www.regulations.gov and insert the docket number, found in brackets in the heading of this document, into the "Search" box and follow the prompts and/or go to the Dockets Management Staff, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852, 240-402-7500.

You may submit comments on any guidance at any time (see 21 CFR 10.115(g)(5)).

Submit written requests for single copies of the draft guidance to the Division of Drug Information, Center for Drug Evaluation and Research, Food and Drug Administration, 10001

New Hampshire Ave., Hillandale Building, 4th Floor, Silver Spring, MD 20993-0002; or to the Office of Communication, Outreach and Development, Center for Biologics Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 71, Rm. 3128, Silver Spring, MD 20993-0002. Send one self-addressed adhesive label to assist that office in processing your requests. See the SUPPLEMENTARY INFORMATION section for electronic access to the draft guidance document.

FOR FURTHER INFORMATION CONTACT: Aaron Weisbuch, Office of Compliance, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Silver Spring, MD 20993-0002, 301-796-3130, Aaron.Weisbuch@fda.hhs.gov or drugtrackandtrace@fda.hhs.gov; or Stephen Ripley, Center for Biologics Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 71, Rm. 7301, Silver Spring, MD 20993-0002, 240-402-7911.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a revised draft guidance for industry entitled "Identifying Trading Partners Under the Drug Supply Chain Security Act." The DSCSA (Title II of Pub. L. 113-54) establishes new requirements to develop and enhance drug distribution security by 2023. It does this, in part, by defining different types of entities in the drug supply chain as *trading partners* (manufacturers, repackagers, wholesale distributors, third-party logistics providers, and dispensers). Among other things, the DSCSA requires that trading partners of manufacturers, wholesale distributors, dispensers, and repackagers meet the applicable requirements for being "authorized trading partners."

In addition, the DSCSA outlines requirements for specific trading partners, including drug product tracing, verification, and licensure requirements (where applicable). This revised draft guidance describes the activities and requirements for entities that are considered to be a manufacturer, repackager, wholesale drug distributor, third-party logistics provider, and/or

dispenser and therefore considered a trading partner under the DSCSA. This guidance revises the draft guidance entitled "Identifying Trading Partners Under the Drug Supply Chain Security Act" that was published on August 24, 2017 (82 FR 40159).

In response to public comments received and policy considerations, FDA has added or revised its current thinking on the status of some entities as trading partners, including private-label distributors, salvagers, and returns processors and reverse logistics providers. The Agency has also provided clarification on certain drug distribution scenarios, including distribution for emergency medical use, office use, non-human research purposes, and research in humans under an investigational new drug application. FDA also addresses the interpretation of section 582(a)(7) of the Federal Food, Drug, and Cosmetic Act, which discusses third-party logistics providers licensure status prior to the effective date of the forthcoming regulations establishing licensure standards.

This revised draft guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The revised draft guidance, when finalized, will represent the current thinking of FDA on "Identifying Trading Partners Under the Drug Supply Chain Security Act." It does not establish any rights for any person and is not binding on FDA or the public. You can use an alternative approach if it satisfies the requirements of the applicable statutes and regulations. This guidance is not subject to Executive Order 12866.

II. Paperwork Reduction Act of 1995

FDA tentatively concludes that this revised draft guidance contains no collection of information. Therefore, clearance by the Office of Management and Budget under the Paperwork Reduction Act of 1995 is not required.

III. Electronic Access

Persons with access to the Internet may obtain the draft guidance at https://www.fda.gov/drugs/guidance-compliance-regulatory-information/guidances-drugs, https://www.fda.gov/regulatory-information/search-fda-guidance-documents,

https://www.fda.gov/vaccines-blood-biologics/guidance-compliance-regulatory-information-biologics/biologics-guidances, or https://www.regulations.gov.

Dated: June 27, 2022.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2022-14345 Filed: 7/5/2022 8:45 am; Publication Date: 7/6/2022]